

REMARKS

Applicants respectfully request reconsideration of the present case in view of the following remarks. Claims 1-33 and 45-49 are currently pending.

Rejections under 35 U.S.C. § 103(a)

Claims 1-7, 15-21 and 45-49 were rejected under 35 U.S.C. § 103(a) as unpatentable over Schiraldi et al. (US Re. 33,093) in view of Valan (U.S. 3,957,966). Applicants respectfully traverse this rejection.

Specifically, the Examiner asserts that Schiraldi teaches a medicament-containing extruded thermoplastic film that includes 20-95% hydroxypropylcellulose, 5-60% ethylene oxide homopolymer and 2-10% plasticizer. The Office Action acknowledges that Schiraldi does not teach the claimed fatty alcohol component and attempts to remedy this deficiency by combining Schiraldi with Valan, asserting that Valan teaches the use of cetyl alcohol and stearyl alcohol as plasticizers in polymeric films. Applicants respectfully assert that a prima facie case of obviousness has not been established for the reasons described below. One of skill in the art would not combine Schiraldi and Valan as asserted by the Office Action for at least two reasons:

1. Because the teachings of Valan about using a fatty alcohol as a plasticizer are very specific to a coating including polyvinylpyrrolidone as a polymer and the prior art shows that fatty alcohols do not act as a plasticizer with all polymers.
2. Because Schiraldi describes the use of 2-10% plasticizer, while Valan teaches inclusion of more than 50% plasticizing agent, one of skill in the art would conclude that the plasticizing agent taught in Valan would not be appropriate for use in the composition of Schiraldi.

For these reasons, as detailed below, Applicants respectfully request withdrawal of the rejections and allowance of the pending claims.

The teachings of Valan are very specific to a coating including polyvinylpyrrolidone.

The Office Action states that Valan teaches the use of stearyl alcohol as a plasticizer in a coating providing for the release of an active material over an extended period of time. The

Office Action cites column 4, line 65 to column 5, line 2. Valan states, “The ratio of N-vinyl lactam to the plasticizing agent may be varied depending upon what type of melt blend or emulsion is desired. For example, melts having more than 50% plasticizing agent form soft and more flexible films and are thus suitable for the coating of food substances or tablets.” (See Valan, Column 4, line 65 to Column 5, line 2.) The focus of Valan is on coatings using N-vinyl lactam, such as polyvinylpyrrolidone or a co-polymer thereof. No other polymers are described.

Valan states that the ability of the combination of its invention to achieve the desired gradual release of the active ingredient is believed to be due to the peculiar physical combination of components. See Valan at Column 6, lines 51 to 59, stating, “Although the mechanism whereby gradual release of the active ingredient is attained over an extended time period from the novel combination of this invention has not absolutely been determined, it is believed with reasonable certainty that the desired effect is achieved because of the peculiar physical combination of components, compatibility, solubility parameters and a co-action during absorption on the surface to which same has been applied.” This statement indicates to one of skill in the art that the same results may not be attained, and indeed are not believed to be likely to be attained, with different combinations of components than the specific components described.

Further, it is known in the prior art that stearyl alcohol does not act as a plasticizer in combination with all polymers. See, for example, the teachings of Tarvainen et al., Predicting Plasticization Efficiency from Three-Dimensional Molecular Structure of a Polymer Plasticizer, 2001, which was cited in the Office Action mailed May 12, 2008.

Tarvainen tested 24 compounds, including cetyl alcohol and stearyl alcohol, for their plasticization efficiency (β) in combination with the film former starch acetate. (See, Tarvainen, Abstract). A decrease in glass transition temperature (T_g) of the film was used as an indicator of plasticization efficiency (page 1760, col. 2): poor plasticizers had a decrease in T_g of less than 30°C (page 1763, col. 2); and compounds that raise the glass transition temperature (T_g) were considered antiplasticizing (page 1763, col. 1). The plasticizing efficiency (β) of the 24 tested compounds is shown in Table 1. Cetyl alcohol had a plasticizing efficiency of 0 ± 0 ; and stearyl alcohol had a plasticizing efficiency of 13 ± 3 . Thus, according to Tarvainen, cetyl alcohol is a poor plasticizer and stearyl alcohol is an antiplasticizing compound.

Since the teachings of Valan are very focused on the combination of polyvinylperrlidone with a fatty alcohol as a plasticizer, and it is known in the prior art that fatty alcohols do not work as plasticizers with all film formers, one of skill in the art would not have found it obvious to make a thermoplastic film including HPC and about 50% fatty alcohol, as asserted in the Office Action.

The Prior Art Teaches Away from the Combination of Schiraldi with Valan

Schiraldi describes the use of 2-10% plasticizer. (Schiraldi, Col. 2, line 46.) In contrast, Valan teaches that inclusion of more than 50% plasticizing agent will form soft and flexible films suitable for food or tablet coating. (See Valan, Column 4, line 65 to Column 5, line 2.) As a result, one of skill in the art would conclude that the plasticizing agent taught in Valan would not be appropriate for use in the composition of Schiraldi.

In determining whether an invention is obvious, the prior art must be considered *in its entirety*, including disclosures that teach away from the claims. See, MPEP § 2141.02. “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference or would be led in a direction divergent from the path that was taken by the applicant.” *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). In fact, proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. *In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986)

When the teachings of Schiraldi, Valan and Tarvainen are taken as a whole, it is clear that the prior art teaches away from the use of cetyl and stearyl alcohol as plasticizers in combination with hydroxypropyl cellulose. Applicants therefore respectfully request withdrawal of this rejection.

Claims 1, 7-14 and 22-33 were newly rejected under 35 U.S.C. § 103(a) as being unpatentable over Schiraldi et al. (US Re. 33,093) in view of Valan, and in further view of Myers et al. (US 2007/0122455) evidenced by Engleson (US 7,153,531). Applicants respectfully traverse this rejection.

As discussed above, the combination of Valan and Tarvainen is improper and does not render the claimed invention obvious. Myers was cited by the Examiner for its teachings of bulking agents, flavorants and sweeteners for use in rapid-dissolving water-soluble films and does not remedy the deficiencies of the primary references. Similarly, Engleson was cited for

the disclosure of dextrose and other carbohydrates as bulking agents in pharmaceutical or food compositions and likewise does not remedy the deficiencies of the primary references. Applicants therefore request withdrawal of this rejection.

Summary

In view of the remarks above, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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Date

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